MAY 3 0 2003

K030587

Attachment I

510(k) SUMMARY

S-TCT Health Inc.
US-ECP

1. Date Prepared: May 27, 2003

2. Submitted by:
S-TCT Health Inc.
13010 Research Blvd., Suite 103
Austin, TX 78750

3. Contact Person:
James S. Turner, Esq.
Swankin & Turner
1400 16th Street, NW, Suite 330
Washington, DC 20036
Tel: (202) 462-8800
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e-mail: jim@swankin-turner.com

4. Device Name: US-ECP

   Common name: External Counterpulsation Device

   Classification name: Device, Counterpulsating, External

5. Predicate Device: The US-ECP is substantially equivalent to:

   Vasomedical Model EECP®-MC2 (K940264), for which clearance was granted February 23, 1995.

6. Description of the Device: The US-ECP is a painless, non-invasive medical device for performing external, sequential counterpulsation. Treatment is administered as the patient lies on the padded top of the device. The patient's calves, thighs, and buttocks are wrapped with specially designed adjustable pneumatic pressure cuffs, similar to blood pressure cuffs. Hoses connect the cuffs to an air pressure/vacuum pump enclosed in the device's base. The patient is also connected to an electrocardiogram to monitor the patient's heart rate. Once everything is properly in place, the device inflates and deflates the cuffs. The design of the cuffs permits significant pressure to be applied to the arteries and veins at

relatively low air pressures. Timing for inflation and deflation is controlled electronically by running the patient's electrocardiogram signals through a microprocessor that monitors the entire treatment process. Each wave of pressure is electronically timed to the patient's heartbeat, so that the increased blood flow is delivered to the heart at the exact moment it is relaxing. When the patient's heart pumps again, pressure in the cuffs is released instantaneously. In short, the device pumps when the patient's heart is resting and releases pressure when the patient's heart is pumping. The intent of the treatment is to encourage cardiac circulation.

7. Intended Use: The intended use of the US-ECP is for the treatment of patients with stable angina pectoris, acute myocardial infarction and cardiogenic shock.

8. Comparison of Technological Characteristics: Technological and functional characteristics of the US-ECP are essentially the same as those of the predicate devices. Differences are speed of microprocessor (US-ECP is a faster, more current model) and cosmetic (e.g., table color).

Signature: _____ *Date*: _____

Gouji Gong, OMD
President, S-TCT Health, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

S-TCT Health Inc.
c/o James S. Turner, Esq.
13010 Research Blvd., Suite 103
Austin, TX 78750

Re: K030587
S-TCT Health External Counterpulsation (ECP) Model US-ECP
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter Pulsating Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: April 2, 2003
Received: April 3, 2003

Dear Mr. Turner:

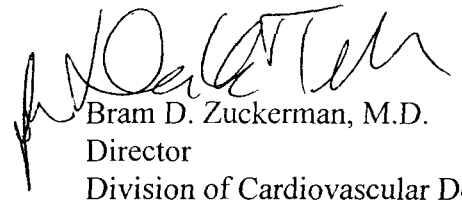
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT C

Indications for Use Statement

510(k) Number: K030587

Device Name: US-ECP
External Counterpulsating Device

Indications for Use: S-TCT Health, Inc.'s US-ECP Model IV is a non-invasive external counterpulsating device intended for use in the treatment of patients with stable angina pectoris, acute myocardial infarction and cardiogenic shock.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K030587

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___